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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,955	12/13/2001	James R. Lupski	HO-P02086US1	2699

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 02/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,955

Applicant(s)

LUPSKI ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-13 drawn to a method of diagnosing myelinopathy in an individual based on an alteration in a periaxin polynucleotide, requiring SEQ ID Nos. 1-77, classified in class 424, subclass 277.1, and subclass 9.322.
 - II. Claim 14, 32-34, drawn to a composition of matter and a kit comprising a polynucleotide, requiring SEQ ID Nos. 3-26, classified in class 536, subclass 22.1.
 - III. Claims 15-16, drawn to a composition of matter comprising a polypeptide, classified in class 530, subclass 350.
 - IV. Claims 17-20, drawn to a method of identifying or screening a compound agent for treating a myelinopathy, classified in class 424, subclass 9.2.
 - V. Claims 21-23, drawn to a method of identifying an upregulator or a drug activity, classified in class 435, subclass 69.1.
 - VI. Claims 24-26, drawn to a method of treating an organism comprising a therapeutically effective amount of a nucleic acid sequence, classified in class 514, subclass 44.
 - VII. Claims 27-28, drawn to a method of treating an organism comprising a therapeutically effective amount of an amino acid sequence, classified in class 514, subclass 2.
 - VIII. Claims 29-31, drawn to a method of treating an organism comprising a therapeutically effective amount of a compound, classified in class 436, subclass 501.
 - IX. Claims 35-40, drawn to a method of detecting the presence or absence of a mutation associated with a myelinopathy, requiring SEQ ID NOS. 1-77, classified in class 435, subclass 6.
3. The inventions are distinct, each from the other because of the following reasons:

Inventions in Group I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product in Group II can be used in a materially different processes such as polymerase chain reaction or purification assays.

Inventions in Group III and IV-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product in Group II can be used in a materially different processes such as polymerase chain reaction or purification assays.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the inventions in Group IV and V have different modes of operation, different functions and different results. For instance, the invention in Group IV is used to identify a compound for treatment of myelinopathy in an individual with an end result of identifying a therapeutic compound. It has different mode of operation with different function and effect.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different

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inventions the inventions in Group V and VI have different modes of operation, different functions and different results. For instance, the invention in Group VI is used to treating an organism with an end result of curing or treating myelinopathy. It has different mode of operation with different function and effect.

Inventions VI and VII-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the inventions in Group VI and VII-VIII have different modes of operation, different functions and different results. For instance, the invention in Group VI can be used independently in a materially different process such as purification and PCR assays. It has different mode of operation with different function and effect.

Inventions VI and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the inventions in Group VI and IX have different modes of operation, different functions and different results. For instance, the invention in Group IX is used to detect a mutation in a sample with an end result of detecting the presence or absence of said mutation in the sample. It has different mode of operation with different function and effect.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

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In this application additionally, if applicants' elect a Group requiring SEQ ID Nos., applicant is required to specify one specific nucleotide sequence for examination. This requirement is made under 1192 O.G. 68 Notice (November 19, 1996), as the examination of more than one sequence in the application would result in an undue search burden on the PTO.

Election of Species:

This application contains claims directed to the following patentably distinct species of the claimed invention:

(1). 3775G>A, (2). 1216G>A, (3). 4075-4077d, (4). 1483G>c, (5). 3394C>G, (6). 3248C>G, (7). 2763A>G, (8). 2645C>T, (9). 306C>T, (10). 149C>G, (11). 2655T>C, (12). 2145T>A, (13). 247ΔC ;

(14). E1259K, (15). A406T, (16). E1359delΔ, (17). E495Q, (18). R1132G, (19). P1083R, (20). 1921M, (21). A882V, (22). T102T, (23). P497P, (24). P885P, (25). R953X, (26). R368X, (27). S929fsX957, (28). R196X, (29). V763fsX774, (30). C715X, (31). R82fsX96.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.


Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
February 13, 2003


JEFFREY FREDMAN
PRIMARY EXAMINER